

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE, AT NASHVILLE

UNITED STATES OF AMERICA,)	
)	
<i>ex rel.</i>)	
)	
TERRELL W. FOX,)	Civil Action No. _____
)	
Plaintiffs,)	FILED UNDER SEAL
)	PURSUANT TO 31 U.S.C. § 3730(b)(2)
v.)	
)	DO NOT PLACE IN PRESS BOX
McKESSON CORPORATION;)	DO NOT ENTER ON PACER
McKESSON CORPORATION d/b/a)	
McKESSON SPECIALTY)	
DISTRIBUTION, LLC; and)	JURY DEMAND
McKESSON SPECIALTY)	
DISTRIBUTION, LLC,)	
)	
Defendants.)	

VERIFIED FALSE CLAIMS ACT COMPLAINT AND
DEMAND FOR A JURY TRIAL

TO THE HONORABLE JUDGES OF THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE:

MAY IT PLEASE THE COURT:

I.
INTRODUCTION

1. Terrell W. Fox (the "Relator") brings this action on behalf of the United States of America against the Defendants for treble damages and civil penalties arising from Defendants' false statements and false claims in violation of the Civil False Claims Act, 31 U.S.C. §§ 3729, *et seq.* The violations arise out of false certifications and from billing for services/products not rendered. Defendant(s) (hereinafter also referred to as "McKesson", "McKesson Specialty", McKesson Specialty Distribution", "Contractor", and/or the "Company"), pursuant to contract(s) with the

United States, was to provide the Centers for Disease Control and Prevention's (hereinafter referred to as "CDC") and/or its providers/patients' vaccines, in support of the CDC's Vaccines for Children Program. These vaccines required careful monitoring for temperature control (also known as "Cold Chain", "Cold Chain Protocol", and/or "Cold Chain Distribution")¹ to ensure product viability so that they could be administered safely to patients. Product integrity to ensure patient safety was the Government's paramount concern. As such, it required extensive expertise from its chosen partner, McKesson, and placed the highest level of contractual requirements to assure public safety relative to the distribution of viable product to children across the country, the Pacific Islands, Puerto Rico, and the Virgin Islands.

2. One of the most significant steps needed relative to public safety was the use of temperature monitors (cold and warm indicators) in every outbound shipment to ensure compliance with all manufacturer and Government contractual shipping temperature settings to validate product safety and viability. Defendants were specifically required under the contracts to keep the vaccines they handled within a specific temperature range. To ensure product viability, Defendants were contractually required to utilize temperature monitors in each vaccine shipment. The temperature monitors approved by the CDC consisted of freeze and warm indicators. Electronic temperature monitors which could indicate exposure to temperatures above and below the appropriate storage temperature range were acceptable. The overall purpose of the temperature devices was to ensure that only viable product would be administered to patients within the program.

3. All temperature monitors to be utilized by McKesson up to November 11, 2007, were electronic monitors received from Cold Chain Technologies, McKesson's supplier. Electronic monitors have settings that can be established by the supplier but only at the direction of their

¹ Cold Chain refers to the transportation of temperature sensitive products along a supply chain through thermal and refrigerated packaging methods and the logistical planning to protect the integrity of the shipments. An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range.

customer, which in this case was McKesson. Both the vaccine manufacturer and CDC contractual requirements were that each shipment was to be within 2-8 degree C (35-46 degree F) and were to never be exposed to freezing temperatures. McKesson, however, instructed monitors to be set from negative 1 to 25 degree C (30-77 degree F) which was clearly out of compliance. The specific settings conveyed by McKesson to Cold Chain Technologies within which the temperature monitors were to be set were as follows:

High Temp 2:25
High Temp 1:12
Low Temp 1:0
Low Temp 2:-1
Upper excursion time (hours): 30
Lower Excursion Time (hours): 2

Accordingly, for high temperatures, this setting indicates that the monitor would only indicate a problem if the temperature was above 25 degree C or was above 12 degree C for over 30 constant hours. For lower temperatures, the setting indicates that the monitor would only indicate a problem if the temperature was below -1 degree C or at or below 0 degree C for 2 constant hours. This would allow refrigerated product to sit at room temperature and never indicate a problem. If these temperature requirements were not met, which clearly was the case here, Defendants were to be entirely responsible for replacing the vaccines at their cost.

4. Not wanting to be liable for substantial losses, Defendants knowingly and intentionally engaged in a scheme to avoid liability by having the temperature monitors which accompanied the vaccines set so that they would not alert that the temperature had varied from the required temperature range. By intentionally failing to set the temperature monitors within the required temperature range (to assure that vaccines were received in a viable condition) and by submitting invoices to the government which purported to have provided these services which, in reality, were not provided, Defendants committed **fraud** against the United States of America.

5. With this knowledge, Defendants continued to ship the vaccines to CDC providers for patients' use in an unacceptable condition. The CDC, its providers/patients and the United States all relied upon the vaccines to be received in a safe and usable condition. Moreover, the Contractor, pursuant to the CDC contracts to which it was a party, was required to determine the viability of vaccine receipts and to report, handle shipments of nonviable vaccines and to return nonviable vaccines. Its contractual responsibilities were to replace, at its cost, the vaccines which were not viable because the required temperature settings had been improperly set on the temperature monitors which accompanied all shipments of vaccines. Defendants failed to comply with any of these requirements causing the United States/CDC damage, as well as risking the health, safety and lives of CDC patients.

6. The temperature settings on the temperature monitors shipped with vaccine shipments were intentionally set so that they would not indicate a breach of the integrity of the required temperature range and, therefore, the Defendants would not be financially responsible to replace the product as required by the CDC contracts. The fraudulent scheme was implemented by Defendants to maximize profits for and protect McKesson from liability under the contracts.

7. As required by the False Claims Act, 31 U.S.C. § 3730(b)(2), the Relator has provided to the Attorney General of the United States and to the United States Attorney for the Middle District of Tennessee a disclosure statement of all material evidence and information related to the complaint herein. The said disclosure statement is supported by material evidence known to the Relator at this filing establishing the existence of Defendants' false claims. Because the said disclosure statement includes attorney-client communications and work product of Relator's attorneys, and is submitted to the Attorney General and to the United States Attorney in their capacities as potential co-counsel in the litigation, the Relator understands this disclosure to be confidential.

II. JURISDICTION AND VENUE

8. This action arises under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*. This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This Court also has jurisdiction pursuant to 28 U.S.C. § 1345 and 28 U.S.C. § 1331.

9. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) and (c) because at all material and relevant times Defendants transacted business in this District.

III. THE PARTIES

10. Relator, Terrell W. Fox, is a citizen of the State of Tennessee residing at 2709 Bering Court, Nolensville, Williamson County, Tennessee, 37135. Relator had been employed by McKesson since 1992. He became the Finance Director of McKesson Specialty Distribution, LLC (hereinafter also referred to as “Specialty”, “McKesson Specialty Distribution”, the “Company”, and/or “Specialty Distribution”) in March of 2007 which was then located in Lewisville, Texas. In this position, Relator reported to Phil Bolger, Vice President and General Manager of Specialty. With respect to the CDC account, Kent Caldwell, a McKesson employee also in the finance area who had previously worked with the CDC on Defendants’ behalf continued to remain responsible for the CDC relationship and contracts.

11. Relator is an “original source” of the information contained in this information to the United States within the meaning of 31 U.S.C. § 3730(e)(4)(B). He has direct, personal and independent knowledge of the information on which the allegations are based and hereby voluntarily provides the information to the Government under the False Claims Act.

12. According to Defendants’ website, McKesson Corporation (“McKesson”) is the largest pharmaceutical distributor in North America with sales in excess of \$112 billion annually. It is ranked fourteenth of the Fortune 500 Companies. A third of all medicines in the United States are

distributed through McKesson. Defendant McKesson supplies more than 40,000 United States pharmacy locations from Wal-Mart to the Department of Veterans Affairs to community pharmacies and hospitals. Its corporate headquarters and principal place of business located at One Post Street, San Francisco, California, 94104. It is also the exclusive national provider for the CDC's Children's Vaccine Program pursuant to federal contract(s) which are the subject of this Complaint.

13. McKesson Specialty Distribution, LLC is a Texas Limited Liability Company with its principal place of business located in Texas, P. O. Box 819066, Dallas, Texas, 75381. Prior to the relocation of McKesson Specialty Distribution, LLC, to Nashville in May 2008, it was located in Lewisville, Texas.

14. The United States of America, through the Centers for Disease Control and Prevention (CDC), is a nationwide provider for vaccines for children ages birth through eighteen (18) years of age pursuant to the Vaccines for Children Program, which was created by the Omnibus Budget Reconciliation Act of 1993 as § 1928 of the Social Security Act. The Program provides federally-purchased vaccines to those who are enrolled in Medicaid or have no health insurance or have health insurance that does not provide immunizations and are seen at a federally-qualified health center or rural health center or are American Indian or Alaska natives. The vaccines are provided to immunize children from various medical conditions such as Diphtheria, Influenza, Hepatitis, Measles, Mumps, Rubella, etc.

IV. GENERAL AVERMENTS OF FACT

15. Pursuant to federal contracts with the United States Government, McKesson and/or McKesson Specialty Distribution, LLC, agreed to store, handle and ship CDC vaccines for the use of children throughout the United States, Puerto Rico, the Virgin Islands and the Pacific Islands. (See footnote 2, *infra*.) Defendants were responsible for the storage, handling and distribution of the vaccines pursuant to these government contracts of which Relator was personally aware. Relator is

specifically aware of Defendants' noncompliance with respect to the contracts which covered shipments of vaccines between March 2007 and November 11, 2007.² Defendant McKesson has a top-down management style with corporate-wide policy decisions, which included the handling, storing, and distribution procedures, also referred to as the "Cold Chain" and/or the "Cold Chain Protocol", implemented with respect to the CDC vaccine contracts. McKesson management personnel involved in fraudulently charging the United States for services which were not rendered and covering up the fraud, which potentially endangered the lives of millions of children, included, but were not limited to: Phil Bolger, Vice President and General Manager, McKesson Specialty Distribution; Pat Blake, President, McKesson Specialty Distribution; and Jennifer Webster, Chief Financial Officer, Specialty Distribution.

16. From March 2007 until October 31, 2007, Terrell W. Fox was employed as Director of Finance for Specialty Distribution at its Lewisville facility located near Dallas, Texas. During this time period and because of Relator's role within the finance area, although with no direct responsibility for the CDC account, he became increasingly aware that the vaccine product shipped pursuant to the CDC contracts with McKesson distribution was being shipped improperly. Specifically, Relator became personally aware that McKesson had mis-set the temperature monitors at a temperature range which did not coincide with the temperature range required pursuant to the CDC contracts. As a result, vaccine was being shipped to children across the country but at a temperature that did not protect the integrity and viability of the vaccine and which, in fact, could cause severe personal injury or even death to the end user.

² The original Solicitation Offer and Award relative to the CDC Children's Vaccine Program was initially issued on November 1, 2005. (See Solicitation No. 2006-N-08248 attached hereto as **Exhibit "A"**.) It was amended and/or modified on May 2, 2006, and again on May 11, 2006. (See Amendments/Modifications of Solicitation No. 08248 attached hereto as **Exhibits "B"** and **"C"**.) The CDC agreements which are controlling relative to this Complaint are Contract No. 200-2006-18246 which arises from Solicitation No. 2006-N-08248 with an effective date of 9/12/2006 (attached hereto as **Exhibit "D"**) and Amendment of Solicitation/Modification Contract No. 00006, which was effective on September 12, 2007, and executed on September 27, 2007. (See **Exhibit "E"** attached hereto.) These two (2) contracts dated 9/12/06 and 9/12/07 are the subject of this Complaint and will be referenced throughout this Complaint. Shipments relative to these two (2) contracts began in February 2007.

17. Mr. Fox became aware of his employer's material breach of the CDC contracts through several ways including, but not limited to: (1) provider alerts, inquiries and/or complaints received via e-mail regarding the temperature monitors which providers thought were not operating correctly or appearing not to reflect the proper settings (see **Collective Exhibit "F"** attached); (2) through inquiries/concerns from McKesson employees working within the vaccine distribution process; (3) his personal testing of temperature monitors as a result of provider/employee inquiries and monitor testings which indicated noncompliance with the contract terms in effect pursuant to the CDC agreements; and (4) two (2) consultant reports.

18. Shipments of vaccine under the CDC contracts at issue began in February of 2007 (see footnote 2, *supra*). As shipments of vaccine increased, operations problems began to emerge with which Relator became aware. Specifically, Relator noticed that the CDC vaccine distribution program appeared to be becoming operationally overwhelming to distribution employees and he began receiving notifications of noncompliance issues regarding shipments of CDC vaccine. After the vaccine shipments had increased, Relator began to be contacted by employees with concerns about the integrity and viability of the CDC vaccines with respect to Cold Chain compliance.

19. Trish Patton, a McKesson employee in charge of customer complaints/resolution, discussed with Relator that she had significant concerns regarding the effectiveness of the temperature monitors. She stated to Mr. Fox that she was unable to obtain adequate responses to her questions regarding the temperature monitors from the operations area in that they ignored her questions or gave unresponsive answers. Trish Patton and Jake Frost, both McKesson employees, were so concerned with the noncompliance of the temperature monitors that they both conducted their own personal testing of the monitors which revealed that the temperature monitors were not set within the range required by the contract or the manufacturer's standards. As a result of these discussions/notifications, Relator ordered a temperature monitor which was being utilized in the CDC vaccine program from the Memphis distribution center to personally test the monitor and it

revealed that the temperature monitor was set so that it would not alert anyone that the temperature range was not set at the range required by the CDC contracts and as proscribed by vaccine manufacturers.

20. Significantly, Mr. Fox received a copy of an e-mail from Cold Chain Technologies, the supplier of the temperature monitors sent with all CDC vaccine product, which expressly confirmed to an inquiring McKesson employee that the temperature monitors were not set correctly and that they were out of compliance with the CDC contract specifications. (See Exhibit "G" attached.) Defendants, and Defendants only, directed Cold Chain as to what temperature to set the temperature monitors. Cold Chain had no flexibility or authority to set the temperature range on the monitors; only McKesson had that authority. Therefore, it relied exclusively on McKesson to provide the temperature range for the temperature monitors to be set. Even if Cold Chain Technologies had improperly set the temperature range on the monitors, under the CDC contracts McKesson is still responsible and, therefore, solely liable for the breach.

21. Within the relevant time period between March 2007 and November 11, 2007, McKesson's noncompliance with the temperature setting on the temperature monitors was further confirmed through Relator's receipt of e-mails which conveyed two (2) studies performed by a consultant, Sensitech, the first of which confirmed improper temperature monitor settings on temperature monitors used with the vaccines in violation of the CDC contracts in effect and the second study which confirmed that the vaccine product had actually been subjected to freezing temperatures which is also improper cold chain handling and in direct breach of the CDC contracts. (See Exhibits "H" and "I".) The consultant's shipment studies showed that four (4) out of six (6) shipments started at negative 1.2 degree C or colder, five (5) out of six (6) shipments were below 2 degree C, three (3) out of six (6) shipments exceeded 8 degree C. Based on the temperature requirements of 2 to 8 degree C for the temperature monitors and the two (2) testings performed by

Sensitech, McKesson should have replaced all product exposed to these conditions pursuant to the contract at its own cost as a result of its product mishandling.

22. After becoming aware of the provider complaints and employee concerns, especially the employee conducted testing of temperature monitors, Relator conducted his own testing of temperature monitors, which also determined McKesson's noncompliance with the CDC's contract specifications and/or the manufacturer's recommended settings regarding temperature monitors. As a result, Relator conducted numerous personal conversations with Phil Bolger, his supervisor, in an attempt to address, correct and resolve the temperature monitor mishandling problem, only to be advised by Bolger that he should "stay out of it, you've got enough to do, you really don't understand, don't worry about it and that he [Bolger] would handle the matter." However, nothing was done by Bolger as a result of Mr. Fox's report of temperature monitor noncompliance with respect to the CDC contracts.

23. As a result of Relator's acquired information relative to the temperature monitors and his employer's intentional violation of the CDC contracts, Mr. Fox reported his findings to other "higher ups" in an attempt to have the matter corrected as soon as possible. He was again ignored.

24. Relator reported the problem with the temperature monitors to Pat Blake, President of Specialty Distribution, Jennifer Webster, Chief Financial Officer of Specialty Distribution, and Phil Bolger, Vice President and General Manager of Specialty Distribution, and Don Walker, a Senior Vice President of Pharma Operations (a Division of McKesson), in an attempt to rectify the temperature monitor problem. They were all aware of the problem regarding the improperly set temperature monitors. (See Exhibit "J".)

25. Despite Relator's attempts to notify his supervisor and "higher ups" regarding the temperature monitor problem, he was unsuccessful in obtaining their assistance in stopping the exposure to recipients of the vaccine across the country due to contaminated vaccine as a result of the improper handling and shipment of the vaccines. Not until Relator went around his supervisor, Phil

Bolger, and requested the assistance of Don Walker, a Senior Vice President of Defendants' Pharma Operations, was there even an acknowledgement of the problem. (See Exhibit "J", *supra*.)

26. As a result of Mr. Fox's finance position, he was provided with monthly reports with respect to the number of CDC vaccine shipments and value of the shipments made by McKesson and, therefore, was aware of the amount and value of the shipments to McKesson Specialty Distribution, LLC and McKesson Corporation. (See Exhibit "K".) It also became clear that Defendants' refusal to correct the matter after being apprised, over and over, was the Company's attempt to avoid responsibility and/or liability pursuant to the CDC contracts which would cause the required reimbursement for every shipped vaccine dose. Each dose of vaccine shipped grossly failed to meet the obligations of the CDC contracts, specifically with respect to the required temperature at which the vaccine must be maintained during handling, storage and shipment.

27. Through information received by Relator while Finance Director at McKesson Specialty Distribution, he calculated that during the relevant period of July 2007 through November 11, 2007, a minimum of Nineteen Million Three Hundred Thirteen Thousand Three Hundred Nineteen (19,313,319) doses were sent out at an average charge of \$46 per dose totaling at a minimum Nine Hundred Million One Hundred Ninety Three Thousand Eight Hundred Two Dollars (\$900,193,802). Further, each and every dose shipped by McKesson Specialty Distribution which make up this total failed to comply with contract specifications for temperature monitor settings and, therefore, specifically breached the CDC contracts which were in effect during this period. Clearly, the Defendants' motive in ignoring the reports of noncompliance by Relator was monetary in nature in that they wished to avoid the replacement cost for all vaccine product shipped which was not in compliance with the CDC contract. To be responsible would have amounted to more than nine hundred million dollars of loss to McKesson just during the relevant period of time, March 2007 – November 11, 2007.

28. As a result of Mr. Fox's position in the finance area of Specialty Distribution, he was provided reports regarding McKesson's monthly invoicing of the CDC contracts. Accordingly, he is personally aware that McKesson invoiced for alleged services they rendered pursuant to the CDC contract on a monthly basis.

29. Because of Phil Bolger's temporary reassignment to another position within McKesson on October 31, 2007, Mr. Fox was placed in Mr. Bolger's position as Interim Vice President and General Manager of McKesson Specialty Distribution, LLC. His first act in this position was to prepare an action plan and to have drafted by the Marketing Department a communication for the implementation of a plan to resolve and correct the temperature monitor problem that existed and of which he was acutely aware. (See Exhibits "L" and "M" attached.) By November 15, 2007, Mr. Fox was instrumental in replacing the electronic temperature monitors used in the CDC vaccine shipments with a chemical temperature monitor system, which remedied the monitor problem.

30. In May of 2008, Mr. Phil Bolger returned to his position of Vice President and General Manager with Specialty Distribution, LLC and contemporaneous therewith, Specialty Distribution, LLC was moved from Texas to Nashville, Tennessee. Mr. Fox was removed from the interim position of Vice President and General Manager and reported directly to Bolger as Vice President of Managed Distribution, a department of McKesson Specialty Distribution, LLC and moved to Nashville in the summer of 2008 to perform his duties regarding that position.

31. Although Relator had no record of poor performance regarding any of the positions he had held with the Company, almost immediately upon reassuming his position of Vice President and General Manager in Nashville, Phil Bolger began to treat Mr. Fox differently and retaliate against him through various mechanisms. Those retaliatory actions included, but were not limited to, embarrassing Mr. Fox in the presence of colleagues and non-employees with no justification. On several occasions, Mr. Bolger made lewd remarks about Relator's wife and her anatomy in front of

colleagues and non-McKesson employees. Although Mr. Fox was successful in the integration project of which he had been an integral part and which was a very important project to McKesson, his integration bonus was intentionally inadequate and far less than was expected.

32. These series of actions taken against Relator in response to and arising out of his efforts to correct an illegal action were intentional and retaliatory. Relator's report of illegality has ultimately caused Relator to lose his job at McKesson. His employment with the Defendant was terminated on July 20, 2012.

A. The Solicitations, Contracts, Amendments/Modifications

33. On or about **September 12, 2006**, McKesson Specialty Distribution, LLC entered into a contract with the United States Government by and through the Centers for Disease Control and Prevention (hereinafter referred to as "CDC"). (See Exhibits "A-E" and footnote 2 for historical perspective of vaccine contracts at issue, *supra*.) The purpose of the agreement(s) was to provide federally purchased vaccine to all children ages birth through eighteen (18) years of age if they are enrolled in Medicaid, have no health insurance or their health insurance does not provide for immunizations, and they are not seen at a federally qualified health center or rural health center, or are American Indian or Alaska native. Another aspect of the program was to centralize and enhance the operating efficiency of the overall vaccine supply chain for all children throughout the United States. The contract required that:

C.4 Distribution Requirements

- A3. The Contractor shall maintain written Standard Operating Procedures (SOP) regarding storage, receiving, packing, shipping, returns, emergency procedures, and stockpile management. **The Contractor shall validate order packing procedures to assure that cold chain integrity is maintained for a minimum of 72 continuous hours.**

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B. Storage, Handling, and Control of Inventory

The Contractor shall handle and store vaccines in such a way as to ensure their continued viability. Such actions shall follow the manufacturer's requirements for receipt, handling, storage, and shipment and all applicable state and federal regulations governing the storage, handling and distribution of vaccines and other biologics, as well as the guidelines contained in U.S. Department of Health and Human Services, Centers for Disease Control and Prevention publications Vaccine Management: Recommendations for Handling and Storage of Selected Biologics updated for 2005 (see attachment J.3). The Contractor may request a waiver in writing from the Contracting Officer for any part of these references but may not implement requested changes unless authorized in writing by the Contracting Officer.

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See **Collective Exhibit "N"** which sets forth three (3) manufacturers' temperature monitor setting standards for the vaccines shipped to the CDC's providers/patients which is 2 degree C to 8 degree C and that vaccine product should not be subjected to freezing temperatures. The fourth attachment to this Collective Exhibit "N" are McKesson's answers to the CDC's questions regarding McKesson's final proposal revision for the Vaccine for Children Program dated June 6, 2006. McKesson acknowledges the required temperature setting as a requirement, see page 11 para. 10.

The contractor and/or McKesson Specialty Distribution is further contractually required as stated below:

- 3.b The Contractor shall pack provider orders to retain their cold chain integrity for at least 72 continuous hours in accordance with:**
- (1) Pertinent manufacturer's package insert instructions for product storage and handling**
 - (2) Applicable state and federal regulations governing the distribution of vaccines and biologics**
 - (3) The following Department of Health and Human Services guidelines:**
 - a) Vaccine Management: Recommendations for Handling and Storage of Selected Biologics, See Attachment J.10.**

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- 3) **Temperature monitors, approved by CDC, that identify to the provider that vaccines received are viable. These measuring devices shall consist of freeze and warm indicators. Electronic temperature monitors that can indicate exposure to temperatures above and below the appropriate temperature are also acceptable.**

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Attachment J.10 to the contract referenced above clearly sets forth that McKesson was contractually bound to assure that the temperature monitors were set at 2 degree C – 8 degree C and they were not.

34. Contractor liability is specifically set forth in the CDC contract entitled “**Liability for Vaccine Inventory and Shipments**” found at C.6, page 19. It provides, in pertinent part, that

- A. **The Contractor shall be responsible for all publicly funded vaccine inventories from the point that it takes possession of the vaccine from the manufacturer to the point that a provider signs for the vaccine upon delivery.**
- C. **The Contractor shall replace, at its own expense and at commercial prices, publicly funded vaccine lost due to the fault of the Contractor or its delivery carrier. Such fault shall include, but is not limited to, mishandling, inappropriate storage, shipment of incorrect vaccine, inappropriate packing, vaccine expiration while in Contractor’s possession, compromise of cold chain, transit time greater than 72 hours, theft, fire, water damage, equipment failure, and loss. Replacement shall be completed within 30 days of loss, and documentation of the replacement shall be provided to the Contracting Officer and the Project Officer (PPOC, as appropriate).**
- D. **CDC will not reimburse the contractor for any cost associated with replacement of vaccines.**

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35. CDC contract number 200-2006-18246 dated September 12, 2006, was continued by an Amendment of Solicitation/Modification of Contract entered into by McKesson Specialty Distribution, LLC and the CDC dated **September 27, 2007**. This contract ran up to and continued beyond November 11, 2007, which is the ending of the relevant period herein. This contract is referred to as Amendment/Modification No. 00006. (**Exhibit “E”**.) This contract provides, in pertinent part, as follows:

B. Storage, Handling, and Control of Inventory.

1. The contractor shall handle and store vaccines in such a way as to ensure their continued viability. Such actions shall follow the manufacturer's requirements from receipt, handling, storage and shipment and all applicable state and federal regulations governing the storage, handling, and distribution of vaccines and other biologics, current good manufacturing processes (CBMP) as well as the guidelines contained in U.S. Department of Health and Human Services, Centers for Disease Control and Prevention Publication Vaccine Management: Recommendations for Handling and Storage of Selected Biologics. The most current version of this publication is available at:
<http://www.cdc.gov/nip/publications/vacmgtbook.htm>

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C4. Distribution Requirements

- A3. The Contractor shall maintain written Standard Operating Procedures (SOP) as described in Section C.8 Standard Operating Procedures, regarding storage, receiving, packing, shipping, returns, emergency procedures, and stockpile management. The SOP must be reviewed by the project officer prior to receipt of the initial vaccine shipment. Proposed changes to the SOP shall be provided to the Project Officer for comment.
4. The Contractor shall validate order packing procedures to ensure the cold chain integrity is maintained for a minimum of 72 continuous hours.

C. Fulfillment of Provider Orders

- 3b. The Contractor shall pack provider orders to retain the cold chain integrity for at least 72 continuous hours in accordance with: 4) the following Department of Health and Human Services Guidelines: Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals.

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- C3. Temperature monitors, approved by CDC, that identify to the provider that vaccines received are viable. These measuring devices shall consist of freeze and warm indicators. Electric temperature monitors that can indicate

exposure to temperatures above and below the appropriate storage temperature are also acceptable.

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4. Shipment of Orders

- e. The Contractor shall choose a mode of shipment whose total in-transit time does not exceed 48 hours, except for the Pacific Island Projects whose total in-transit time does not exceed 60 hours.

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With respect to contractor liability for vaccine inventory and shipments, McKesson Specialty Distribution is bound by the section of the contract which provides for contractor liability (see, C.6)

- C. **The Contractor shall replace, at its own expense and at commercial prices, publicly funded vaccine lost due to the fault of the contractor or its delivery carrier. Such fault shall include, but is not limited to, mishandling, inappropriate storage, shipment of incorrect vaccine, inappropriate packing, vaccine expiration while in contractor's possession (e.g., vaccine that expires as a result of not using FEFO practices), transit time greater than 72 hours, theft, fire, water damage, equipment failure and loss. Replacement shall be completed within 30 days of loss and documentation of the replacement shall be provided to the contracting officer and the project officer.**

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- G. In order to determine that responsible party for replacement vaccine in arrears, the contractor shall be responsible for analyzing vaccine lost while in transit to provider locations and during the 2 hour receipt, validation and storage process. Specifically, the contractor should adhere to the following criteria:
 - (1) **Ensure temperature monitors and vaccines are returned to the contractor's warehouse for analysis.**

- (4) Ensures Contractor staff (return specialist) review/documents when the temperature monitor began to read "negative".

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IV. CAUSES OF ACTION

A. False Billings for Services Not Rendered

30. Relator realleges and incorporates the allegations of Paragraphs 1 through 29 above as if fully set forth herein.

31. Defendants knowingly and falsely represented that they had complied with the terms and conditions of Contract No. 200-2006-18246 and Amendment of Solicitation/ Modification of Contract No. 00006 when, in fact, Defendants knew that they had intentionally failed to provide temperature monitors set at the proper temperature setting range to be sent along with vaccines to the end users pursuant to the requirements of the CDC contracts. Specifically, Defendants intentionally breached the CDC agreements by failing to comply with the shipping requirements as stated in the Vaccine Management Recommendations for Storage and Handling of Selected Biologicals dated January 2007, which is incorporated by reference into both referenced CDC contracts. Shipping requirements, as stated in the Vaccine Management publication, clearly state the vaccine:

Should be shipped in insulated container. Maintain temperature at 35 degrees to 46 degrees Fahrenheit (2 degrees to 8 degrees C). Do not freeze or expose to freezing temperatures.

See Page 1, *et seq.*, except that McKesson did not handle the vaccines that required freezing.

32. As the proof has been set forth herein, Defendants have failed to ship vaccine product in accordance with the shipping requirements stated herein. There is also proof that vaccine was subjected to freezing temperatures and/or that it was frozen, which is a further breach.

33. Defendants combined, conspired, and agreed to defraud the United States by knowingly submitting false claims to the United States for the purpose of getting the false or fraudulent claims paid or allowed and committed the other overt acts set forth above in furtherance of that conspiracy, all in violation of 31 U.S.C. § 3729(a)(3), causing damage to the United States.

B. Retaliation in Violation of 31 U.S.C. § 3730(h)

34. Relator realleges and incorporates the allegations of paragraphs 1 through 33 as if fully set forth herein.

35. After his report of illegality to Defendants, *qui tam* Plaintiff was harassed and terminated from his employment with Defendants as a result of his lawful acts done in furtherance of this action, including complaints to corporate officials regarding the false claims described herein. This harassment and firing was in violation of 31 U.S.C. § 3730(h).

36. As a direct and proximate result of this unlawful and discriminatory harassment and firing, Plaintiff has suffered emotional pain and mental anguish, together with lost wages and special damages associated with his efforts to obtain alternative employment, in an amount to be proven at trial.

WHEREFORE, all premises considered, the Relator respectfully requests this Court to enter judgment against the Defendants, and each of them jointly and severally, and grant the following relief:

1. That the United States of America be awarded damages in the amount of three (3) times the alleged fraud or false claims submitted to the CDC by the Defendants, or any of them, as alleged in this Complaint, as the Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*, as enacted and enforced may provide; and

2. That civil penalties of Eleven Thousand Dollars (\$11,000.00) be imposed for each and every false claim that Defendants presented to the United States of America through the CDC or its customers or patients throughout the United States; and

3. That pre- and post-judgment interest be awarded, along with reasonable attorney's fees, costs and expenses which the Relator has necessarily incurred in bringing and pressing this case; and

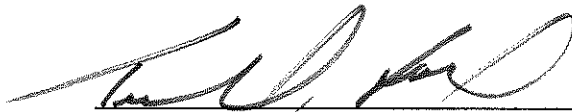
4. That the Court grant permanent injunctive relief to prevent any recurrence of the violations of the False Claims Act for which redress is sought in this Complaint; and

5. That Relator be awarded the maximum allowed to him under the False Claims Act; and

6. For Cause of Action B, that the Relator be granted all relief necessary to make him whole, including, but not limited to, two (2) times his backpay and other compensatory damages sustained as a result of Defendants' harassment, retaliation and termination; and

7. That this Court award such other and further relief as may be lawful and just in the premises; and

8. Relator, on behalf of himself and the United States, demand a jury trial on all claims herein alleged.

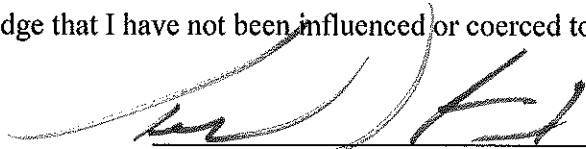

Terrell W. Fox

STATE OF TENNESSEE)
)
COUNTY OF DAVIDSON)


VERIFICATION

Appeared before me the undersigned Notary Public, Terrell W. Fox who, after being placed under oath, did depose and say the following:

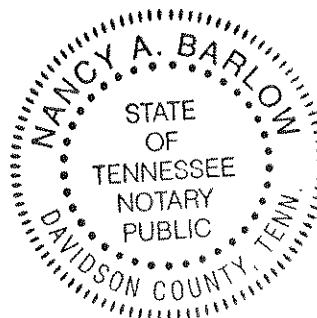
My name is Terrell W. Fox and I am over the age of twenty-one (21) years, of sound mind and not under the influence of any drugs or medications. I have reviewed the foregoing Complaint and each exhibit attached thereto. The statements and information contained in the said Complaint are true and correct and based on either my firsthand knowledge, the contents of the said exhibits or the applicable Federal Acquisition Regulations. I make this Complaint voluntarily as my own free act and deed and further acknowledge that I have not been influenced or coerced to do so.


Terrell W. Fox

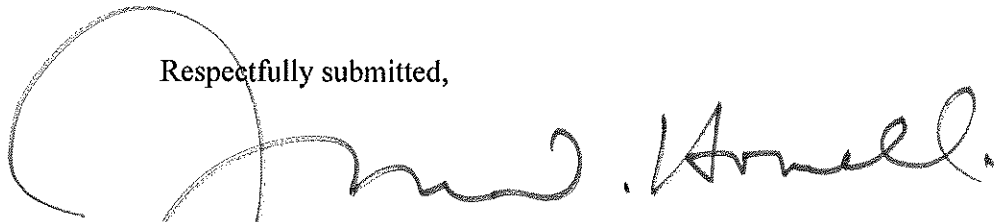
Sworn to and subscribed before me
this 24th day of July, 2012


Notary Public

My Commission Expires: March 4, 2013



Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read "Trevor W. Howell". The signature is written over a horizontal line.

Trevor W. Howell, #9496
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